

Extended Summaries

Transgenic Crops: New Perspectives in Crop Protection

The following are extended summaries based on presentations at the meeting 'Transgenic Crops: New Perspectives in Crop Protection' organized by L. G. Copping on behalf of the Physicochemical and Biophysical Panel of the SCI Pesticides Group and held at 14–15 Belgrave Square, London on 11 March, 1997. They are entirely the responsibility of the authors and do not necessarily reflect the views of the Editorial Board of Pesticide Science.

Patenting Life? The Opportunities for Protecting Molecular Biological Inventions in Europe

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The European Patent Office (EPO) has already granted patents having claims to isolated DNA sequences, vectors containing such sequences and cells transformed by such vectors. Both human, bacterial and plant gene sequences are potentially patentable in Europe.^{1–5}

Article 53(a) of the European Patent Convention (EPC) allows for applications to be rejected if they are 'immoral'. The EPO applies this exception to patentability only for the most extreme cases, and so far no patent application relating to genetic engineering of animals or plants has been completely rejected after third-party opposition on this ground.^{2,4,5}

Article 53(b) EPC excludes from patentability 'plant and animal varieties as such'. There is not at present a system for protecting animal varieties. New plant varieties have been defined by the Technical Board of Appeal of the EPO as 'any plant grouping within a single botanical taxon of the lowest known rank which is characterized by at least one single transmissible characteristic distinguishing it from the other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics'.⁵ Plant groups which are distinct, uniform and stable (DUS) may be protectable as plant varieties under the 1991 Convention for the Protection of New Varieties of Plants. Nonetheless, the EPO has previously granted patents which include claims covering plants, seeds and propagating materials, but not varieties as such.^{6–9} In its

Decision of 26 July 1983 the Technical Board of Appeal said:

A claim directed to a propagating material, treated with chemical agents, for certain genera of plants (in this case cultivated plants) without specific varieties being claimed individually, does not contravene the prohibition on the patenting of plant varieties in Article 53(b) EPC.¹⁰

In its Decision dated 10 November 1988 the Technical Board of Appeal said:

Hybrid seed and plants from such seed, lacking stability in some trait of the whole generation population, cannot be classified as plant varieties within the meaning of Article 53(b) EPC.⁹

In its Opinion dated 27 November 1995 the Enlarged Board of Appeal of the EPO said:

In Decision T 356/93 (Plant Genetic Systems NV/Herbicide Resistant Plants) it was held that a claim defining genetically modified plants having a distinct stable, herbicide-resistant genetic characteristic was not allowable under Article 53(b) EPC because the claimed genetic modification itself made the modified or transformed plant a 'plant variety' within the meaning of Article 53(b) EPC. . . . This finding is not in conflict with the findings in either of Decisions T49/83 (Ciba-Geigy/Oxime Treatment of Seeds) or T19/90 (Harvard/Oncomouse).¹¹

The Board thus distinguished between (i) inventions in which the modification is not inheritable (e.g. a chemical modification of a plant cell¹⁰ or the introduction into a mouse embryo of a cancer-causing gene² and (ii) inventions in which a genetic modification causes a characteristic which is distinctive and stable in succeeding generations (e.g. genetic herbicide-resistance).⁵

Unless or until this Opinion is overturned it seems that it will be difficult or impossible to uphold claims to genomically stably modified crops as such.

It is believed that many interested parties in the Industry, Patent Practitioners, and even some EPO Examiners think that the Decision T 356/93 rejecting the Plant Genetic Systems NV patent was wrong. Another case relating to transgenic plants in which the same problem arises has now been rejected by the EPO Examining Division and is currently under Appeal.¹² Claim 19 of the patent application reads as follows:

A transgenic plant and the seed thereof comprising recombinant DNA sequences encoding

- (a) one or more lytic peptides, which is not lysozyme, in combination with;
- (b) one or more chitinases; and/or
- (c) one more β -1,3-glucanases

in a synergistically effective amount.

The grounds of appeal were filed by the Patent Attorney representing Novartis on 5 November 1996. In the Grounds of Appeal he said:

A given plant cannot be considered as a variety simply because it carries some additional gene(s) introduced by genetic engineering that cause(s) a distinct and stable genetic characteristic while the remainder of the genome can be nonhomogeneous and genetically unstable. A variety cannot be defined by a single new trait but only by substantially all of its traits in combination. Hence, a plant variety is always made up of an *individualized* (unique genome or a combination of unique genomes, but can never be characterized by a *generalized* genotype, on which the plants of pending claims 19 to 22 are based. As long as a claim does not require overall genetic homogeneity and stability, it simply does not solely encompass plant varieties. Furthermore, a plant produced by genetic engineering is not automatically a plant variety, even if the starting material applied was a plant variety.

None of pending claims 19 to 22 requires overall genetic homogeneity and stability of the transgenic plants addressed therein. Thus, none of these claims specifically relates to a 'plant variety' in the sense of Article 53(b) EPC.

The Appeal Board of the EPO is due to decide on the case at Oral Proceedings on 13 October 1997. If the Appeal is successful and the patent claims are granted it will re-establish the possibility for patenting genomically stably modified crops as such in Europe. If this result occurs, it will be in line with the current form of wording of the European Council and Parliament's proposal for a Directive on the Patentability of Biotechnological Inventions. The Directive clearly envisages the possibility of patenting a plant having a stable and transmissible genetic characteristic, because in the draft version of the Directive dated 25 June 1997 it is stated as follows.

The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that

process and to any other biological material derived from the biological material directly obtained through multiplication or propagation in an identical or divergent form and possessing those same characteristics.

Whereas this Directive shall be without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are in general patentable provided that the practicability of the invention is not technically confined to a single plant or animal variety ...

Whereas a plant totality which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises plant varieties ...

The outcome of the Novartis Appeal case at the EPO will be of great interest and significance to those concerned with the opportunities for protecting molecular biological inventions relating to transgenic crops and crop protection.

REFERENCES

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2. EP-B-0169672 Harvard Oncomouse; Appeal Decision T19/90 (1990).
3. EP-B-0112149 Howard Florey Institute; Human Relaxin Gene; Opposition (1991).
4. EP-B-0122791 Lubrizol; Plant Gene Expression (1989).
5. EP-B-0242236 Plant Genetic Systems NV; Herbicide Resistance; T356/93 (1995).
6. EP-B-0271988 Zeneca; Delayed Softening of Tomatoes (1995).
7. EP-B-0341885 Zeneca; Delayed Softening of Tomatoes (1995).
8. EP-B-0301749 Agracetus Inc; Transformed Soyabean Plants (1994).
9. EP-B-0044723 Lubrizol; Production of Hybrid Plants; Appeal Decision T320/87 (1988).
10. EP-B-0010588 Ciba-Geigy Oxime Treatment of Seeds, Appeal Decision T49/83 (1983).
11. Enlarged Board of Appeal Decision GP G03/95 (1995).
12. EP-A-0448511 Novartis; Transgenic plants that contain genes that are able to express lytic peptides and hydrolytic enzymes; Appeal (1996).

Is This the End of Chemical Plant Protection?

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When new techniques and concepts allow progress to be made on problems that have long proved to be intractable to established methodologies, this can initially result in over-optimistic expectations of what the new techniques can achieve. The idea that transgenic crop plants could eventually eliminate pesticide use may